

Date of Approval: August 16, 2021

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-618
Zoletil™ for Injection
(tiletamine and zolazepam for injection)
Injectable Solution
Dogs

Provides for a new indication, Zoletil™ for Injection administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

Sponsored by:

Virbac AH, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-618

B. Sponsor

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Drug Labeler Code: 051311

C. Proprietary Name

Zoletil™ for Injection

D. Drug Product Established Name

tiletamine and zolazepam for injection

E. Drug Enforcement Agency (DEA) Schedule

Zoletil™ for Injection (tiletamine and zolazepam for injection) is a nonarcotic, nonbarbiturate dissociative and minor tranquilizing anesthetic and is a Class III controlled substance.

F. Pharmacological Category

Anesthetic, DEA Schedule Class III controlled substance

G. Dosage Form

Injectable solution

H. Amount of Active Ingredient

100 mg/mL total (equivalent to 50 mg/mL tiletamine and 50 mg/mL zolazepam)

I. How Supplied

Individual vials of 5 mL solution when reconstituted

J. Dispensing Status

Prescription (Rx)

K. Dosage Regimen

Intravenous (IV) For Induction of Anesthesia Followed by Maintenance with an Inhalant Anesthetic: In dogs, for induction of anesthesia, administer Zoletil™ for Injection intravenously at 1-2 mg/lb (2.2-4.4 mg/kg) body weight to effect. Zoletil™ for Injection should be administered slowly, over 30-45 seconds;

after approximately 30-60 seconds, the dog's level of consciousness, muscle relaxation, and jaw tone should be assessed to determine the ability to intubate. If after waiting 60 seconds the dog's level of anesthesia is not sufficient for successful intubation, additional Zoletil™ for Injection may be administered; the total dose should not exceed 2 mg/lb (4.4 mg/kg) body weight.

L. Route of Administration

Intravenous injection

M. Species/Class

Dogs

N. Indication

Zoletil™ for Injection administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

O. Reference Listed New Animal Drug (RLNAD)

Telazol®; tiletamine and zolazepam for injection; NADA 106-111; Zoetis Inc.

P. Effect of Supplement

This supplement provides for the addition of a new indication, the intravenous administration for induction of anesthesia followed by maintenance with an inhalant anesthetic in dogs.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-618, dated June 23, 2017, contains a summary of data that demonstrates bioequivalence of the drug for intravenous administration for induction of anesthesia followed by maintenance with an inhalant anesthetic in dogs .

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Zoletil™ for Injection :

FOR USE IN DOGS AND CATS ONLY.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The

data demonstrate that Zoletil™ for Injection, when used according to the label, is safe and effective for the indications listed in Section I.N. above.